Remarks

Claims 1-31 are pending in the application and are presented for the Examiner's review and consideration. Claims 1, 4, 5, 10-13, 15, 16, 19, 21, 22, and 26-31 have been amended. Applicant believes the claim amendments, cancellation, additions, and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Effective Filing Date

The present application claims priority to a number of prior filed applications. In the Office Action, it is asserted that the disclosures of Application Nos. 09/976,396; 09/941,185; 09/566,070; 09/737,380; 09/569,020; 09/483,676; 09/798,870; 09/526,949, and 09/789,621 fail to provide adequate support or enablement such that claims 1-31 are not entitled to the benefit of the prior applications. It is further asserted that since the disclosure of Application No. 10/191,751 is in compliance with the requirements of the first paragraph of 35 U.S.C 112, the claims are entitled to the benefit of this filing date, i.e. July 8, 2002.

Applicant disagrees. For example, Application No. 09/941,185 discloses a modular joint implant. Relevant disclosure in this application includes Fig. 40 and paragraphs [0309]-[0322], which teach an implant formed of two or more portions. Accordingly, Applicant submits that the present application is entitled to an effective filing date at least as early as the filing date of Application No. 09/941,185, i.e. August 28, 2001.

35 U.S.C. §102 Rejections

Claims 1-31 were rejected under 35 U.S.C. §102(B) as being anticipated by Bouvet (FR2,682,287). As set forth below, Applicant respectfully submits that these rejections should be withdrawn.

As an initial matter, Applicant has recently obtained a publicly available English language translation, a copy of which is enclosed herewith. Bouvet concerns a knee prosthesis, i.e., elements for restoring the knee joint between the femur, the tibia, and the knee cap. (Page 1). The object of Bouvet is to devise a prosthesis whose structure is such as to limit, insofar as possible, wear and tear on the elements cooperating with one another frictionally or by an equivalent modality. (Page 1).

Both figures 1 and 2 of Bouvet show a knee prosthesis comprising a femoral component suitable for attachment to the femur 2, the tibial plateau suitable for attachment to the tibia 4, and a patellar button 5. (Page 2). Femoral component 1 has a substantially U shape base 6 and one of the sides 7 of the U defining two condylar surfaces 8, 9, . . ., the other side 10 of the U defining a trochlea 11. (Id.)

As illustrated in the figures, the two condylar surfaces 8, 9 are obviously separated, but are joined to each other by a bridge 15 that has an arch shape, situated in the space delimited by the concave face 25 of the condylar surfaces 8, 9. (Id). In a known manner, the two condylar surfaces comprise attachment means for attachment to the femur. (Id). These means are constitute by, for example, lugs integral to concave face 25 of the condylar surfaces.

For the trochlea 11 to be constructed of a different material 23 from that 21 of the condylar surfaces, it is advantageous to fabricate these two elements in two separate parts, the trochlea comprising attachment means for attachment to the femur. (Id). In the interest of secureness, however, and to facilitate its implantation, the trochlea 11 further comprises a tab 29 designed to be inserted between the two condylar surfaces 8, 9 and beneath the arch of bridge 15. (Id).

In addition, the fact that the trochlea 11 is disassociated from the condylar surfaces 8,9 makes it possible for the stresses applied at the level of the condylar surface not to be transmitted to the trochlea, and vice versa. (Page 3). As a result, the thickness of these two elements can be smaller than the thickness of the corresponding elements in the prostheses of prior art, which makes it possible to preserve a large quantity of bone on the lower femoral head, and thus makes the implantation of the prosthesis still more secure. (Id)

As such, Bouvet discloses a femoral component of the knee prosthesis having an condylar portion and the trochlea portion. The condylar portion includes two condylar surfaces provided in a spaced apart arrangement, connected by an arch bridge. The condylar surfaces have an attachment means for attachment to the femur. The trochlea portion is also disclosed as having an attachment means for attachment to the femur, separate from the condylar portion.

However, Bouvet fails to disclose that the condylar portions and the trochlea portion are affixed together. Bouvet simply discloses that the trochlea portion has a tab which is positioned through the arch bridge, as is clearly shown in figure 2. There is no disclosure in the specification of the figures that describes affixing the condylar portions and the trochlea portion together. In fact, Bouvet teaches against such a formation, expounding on the benefits of the condylar portions and the trochlea portion being disassociated, namely, the prevention of the transmission of stress between the condylar surfaces and the trochlea portion (and vice versa).

Accordingly, Applicant submits that Bouvet fails to disclose that the condylar portions and the trochlea portion are affixed together. Furthermore, Bouvet fails to provide any suggestion or motivation to affix the condylar portions and the trochlea portion together, as this is directly taught against.

In contrast, the present invention discloses an implant with interconnectable portions. (¶[0360]). In order to enable surgery on a knee portion 76 of a patient's leg 70 to be conducted through an incision 114 of relatively small size, the implant may advantageously be formed in two or more portions (FIG. 40). (Id). The portions of the implant are sequentially moved through the incision 114 into engagement with the distal end portion 124 of the femur 126 and/or the proximal end portion 212 of the tibia 214. (Id).

As the portions of the implant are sequentially moved through the incision 114, they are positioned in engagement with one or more of the bones, that is, the femur 126 and/or the tibia 214 in the leg 70 of a patient. (¶[0361]). After the plurality of portions of the implant have been moved through the incision 114 and positioned in engagement with the femur 126 and/or tibia 214, the portions of the implant are interconnected to form a unitary implant. (Id).

It is contemplated that the portions of the implant may be interconnected while they are disposed in the patient's body and in engagement with either the femur 126 and/or tibia 214 in many different ways. (¶[0362]). For example, the portions of the implant may be bonded together to form a one piece implant. The portions of the implant may be bonded together by the application of energy in any one of many different forms to a joint between portions of the implant. (Id).

It is also contemplated that the separate portions of the implant could be mechanically interconnected. (¶[0363]). This could be done with a fastener which extends between portions of the implant. (Id). Alternatively, a retainer member such as a rod or bar could extend between portions of the implant. (Id).

As such, the present invention discloses an implant formed from two or more portions that are individually positioned into a body of a patient. After insertion into the body of the patient, the portions are affixed together forming a unitary implant. The portion can be affixed together by bonding or mechanical means.

As previously discussed, Bouvet fails to disclose, suggest or provide motivation for affixing the implant portions together.

Claim 1 recites, *inter alia,* a modular joint implant comprising a plurality of separate implant portions. The separate implant portions are affixable together to form a unitary implant having at least one articulating surface, wherein the plurality of separate implant portions are affixable to at least one joint member of a joint. Claims 13, 21, 22, and 29 include similar elements.

In light of the foregoing, Applicant submits that claims 1, 13, 21, 22, and 29 are patentable Bouvet. Furthermore, claims 1-12 depend from claim 1; claims 14-20 depend from claim 13; claims 23-28 depend from claim 22; and claims 30 and 31 depend from claim 29. Accordingly, Applicant submits that these claims are patentable over Bouvet at least for the same reasons.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of $120.00 under 37 C.F.R 1.17(a)(1) for a one month extension of time is believed due and is being paid via credit card payment. However, please charge any fees (or credit any overpayment of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A03-12A).

Respectfully submitted,

Paul D. Bianco, Reg. # 43,500

Customer Number: 33771
Paul D. Bianco
FLEIT KAIN GIBBONS GUTMAN BONGINI & BIANCO
21355 East Dixie Highway, Suite 115
Miami, Florida 33180
Tel: 305-830-2600; Fax: 305-830-2605
e-mail: pbianco@focusonip.com

Enclosure

(19) FRENCH REPUBLIC

NATIONAL INSTITUTE
OF INDUSTRIAL PROPERTY

PARIS

(11) **Publication No.:** 2 682 287
(To be used only in
ordering copies)

(21) **National Registration No.** 91 12531

(51) Int. Cl.^{6} **A 61 F 2/38; A 61 L 27/00**

(12) PATENT APPLICATION A1

(22) **Filing date:** October 11, 1991

(30) **Priority:**

(43) **Date application laid open to the public:** April 16, 1993 Bulletin 93/15.

(56) **List of documents cited in preliminary search report:** The *search report has not been prepared as of the publication date of the application.*

(60) **References to other related national documents:**

(71) **Applicant(s):** BOUVET, Jean-Claude – FR.

(72) **Inventor(s):** BOUVET, Jean-Claude.

(73) **Proprietor(s):**

(74) **Agent:** Abritt.

(54) Knee prosthesis.

(57) The present invention concerns knee prostheses.

The prosthesis of the invention is characterized essentially by the fact that it comprises a femoral component 1, a tibial plateau 3 and a patellar button 5, the femoral component having substantially a U shape, the base 6 and one of the sides 7 of the U defining two condylar surfaces 8, 9 suitable for cooperating frictionally with the tibial plateau 3, the other side 10 of the U defining a trochlea 11, the two condylar surfaces, the surface of the tibial plateau, the trochlea and the patellar button being made respectively of a first 21, a second 22, a third 23 and a fourth 24 material, the third material having a hardness that is lower than those of the first material and the fourth material.

Knee prosthesis

The present invention concerns knee prostheses, i.e., elements for restoring the knee joint between the femur, the tibia and the kneecap.

A knee prosthesis essentially composed of a femoral component suitable for attachment to the femur and a tibial plateau suitable for attachment to the tibia is already known. The femoral component assumes a substantially U shape, with the base and one side of the U defining two condylar surfaces moving in relation to the corresponding surfaces of the tibial plateau, and the other side of the U defining a trochlea against which the kneecap abuts and moves, the kneecap being affixed to a patellar button.

In the current embodiments, the U-shaped femoral component is made entirely of metallic material, for example stainless steel, and the patellar button is of a softer and less durable material, for example plastic or the like, notably polyethylene.

The structure reviewed above and its mode of implementation give relatively satisfactory results. However, it is commonly observed that the longer the life of such a prosthesis, the greater the comfort of the patient wearing it, if only because he does not have to think about undergoing too-frequent surgical procedures

Thus, engineers are always trying to develop improvements that can be hoped to increase the life of this type of prosthesis.

The object of the present invention is, therefore, to devise a prosthesis whose structure is such as to limit, insofar as possible, wear and tear on the elements cooperating with one another frictionally or by an equivalent modality.

More precisely, the present invention is directed to a knee prosthesis comprising a femoral component suitable for attachment to the femur, a tibial plateau suitable for attachment to the tibia, and a patellar button, said femoral component having substantially a U shape, the base and one of the sides of said U defining two condylar surfaces suitable for cooperating frictionally with said tibial plateau, the other side of said U defining a trochlea, characterized by the fact that the two condylar surfaces, the surface of said tibial plateau, the trochlea and said patellar button are made respectively of a first, a second, a third and a fourth material, said third material having a hardness that is lower than that of said fourth material and that of said first material.

Other characteristics and advantages of the present invention will emerge in the course of the following description, provided with reference to the accompanying drawings which are to be construed as illustrative and in no way limiting, wherein:

Fig. 1 is a perspective view of an embodiment of a knee prosthesis according to the invention, and

Fig. 2 shows a prosthesis implemented according to the embodiment illustrated in Fig. 1, one part of which is implanted on a femur and the other on a tibia.

Both figures, 1 and 2, show a knee prosthesis comprising a femoral component suitable for attachment to the femur 2, a tibial plateau 3 suitable for attachment to the tibia 4, and a patellar button 5. Femoral component 1 has a substantially U shape, the base 6 and one of the sides 7 of the U defining two condylar surfaces 8, 9 suitable for cooperating frictionally with two corresponding surfaces 12, 13 of the tibial plateau 3, the other side 10 of the U defining a trochlea 11.

According to one important characteristic of the prosthesis according to the invention, the two condylar surfaces 8, 9, the surfaces 12, 13 of tibial plateau 3, the trochlea 11 and the surface 14 of patellar button 5 are made respectively of a first 21, a second 22, the [sic] third 23 and a fourth 24 material, the third material having a hardness that is lower than those of the first and fourth materials.

In a preferred embodiment, the first material 21 has a hardness equal to or greater than that of the second material 22 and the first 21 and fourth 24 materials are identical.

In a possible embodiment, the first 21 and fourth 24 materials are metallic materials and the third material 23 is a plastic material.

As illustrated in the figures, the two condylar surfaces 8, 9 are obviously separated, but are joined to each other by a bridge 15 that has an arch shape, situated in the space delimited by the concave face 25 of the condylar surfaces 8, 9. In a known manner, the two condylar surfaces naturally comprise attaching means for attachment to the femur. These means are constituted by, for example, lugs 26 integral to concave face 25 of the condylar surfaces.

For the trochlea 11 to be constructed of a different material 23 from that 21 of the condylar surfaces, it is advantageous to fabricate these two elements in two separate parts, the trochlea 11 comprising attaching means for attachment to the femur 27, again constituted by lugs integral to the concave face 28 of the trochlea and designed to be implanted, for example with cement, in the femur 2.

In the interest of secureness, however, and to facilitate its implantation, the trochlea 11 further comprises a tab 29 designed to be inserted between the two condylar surface 8, 9 and beneath the arch of bridge 15.

The applicant has constructed prototypes that have given complete satisfaction, in which the first 21 and fourth 24 materials were stainless steel and the second 22 and third 23 materials polyethylene.

The knee prosthesis described above undeniably possesss advantages over the prior art. Since the frictional area on the trochlea is larger than that of the button, the fact that the patellar button is made of a harder material than the trochlea brings about a sizable decrease in frictional wear of these two elements. The amount of wear particles from the materials is thereby reduced, and thus also the number of macrophages that tend to agglutinate around such prostheses, between them and the bones on which they have been implanted, and which are the chief cause of detachment of these prostheses.

In addition, the fact that the trochlea 11 is disassociated from the condylar surfaces 8, 9 makes it possible for the stresses applied at the level of the condylar surfaces not to be transmitted to the trochlea, and vice versa. As a result, the thicknesses of these two elements can be smaller than the thicknesses of the corresponding elements in the prostheses of prior art, which makes it possible to preserve a large quantity of bone on the lower femoral head, and thus to make the implantation of the prosthesis still more secure.

To clarify this last advantage, Fig. 2 shows in chain-dotted lines 40 the position of the inner face, in contact with the femur, of a femoral component of prior art if it had been implanted in place of a femoral component according to the invention. The additional quantity of bone of the femur 41 that can be preserved for the installation of the knee prosthesis according to the invention is clearly evident.

CLAIMS

1. A knee prosthesis comprising a femoral component (1) suitable for attachment to the femur (2), a tibial plateau (3) suitable for attachment to the tibia (4), and a patellar button (5), said femoral component having substantially a U shape, the base (6) and one of the sides (7) of said U defining two condylar surfaces (8, 9) able to cooperate by friction with said tibial plateau (3), the other side (10) of said U defining a trochlea (11),
characterized by the fact that the two condylar surfaces, the surface of said tibial plateau, the trochlea and said patellar button are made respectively of a first (21), a second (22), a third (23) and a fourth (24) material, said third material (23) having a hardness that is lower than that of said fourth material (24) and that of said first (21).

2. The prosthesis as recited in claim 1, characterized by the fact that said first material (21) has a hardness equal to or greater than that of said second material (22).

3. The prosthesis as recited in either of claims 1 and 2, characterized by the fact that said first (21) and fourth (24) materials are identical.

4. The prosthesis as recited in claim 3, characterized by the fact that said first (21) and fourth (24) materials are metallic materials and in that said third material (23) is a plastic material.

5. The prosthesis as recited in one of the preceding claims, characterized by the fact that the two condylar surfaces (8,9) are rendered integral to each other by an arch-shaped bridge (15).

6. The prosthesis as recited in one of the preceding claims, characterized by the fact that it further comprises means for attaching (26) the two condylar surfaces to the femur.

7. The prosthesis as recited in either of claims 5 and 6, characterized by the fact that said trochlea (11) comprises a tab (29) that is inserted between the two said condylar surfaces (8, 9) and underneath the arch of said bridge (15).

8. The prosthesis as recited in claim 4, characterized by the fact that said first (21) and fourth (24) materials are of stainless steel and in that said third material is polyethylene.

9. The prosthesis as recited in one of the preceding claims, characterized by the fact that it further comprises menas for attaching (27) said trochlea (11) to the femur.